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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/917,475	07/27/2001	Brian D. Andresen	IL-10380	1094

7590 05/21/2003

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EXAMINER
ROGERS, DAVID A

ART UNIT	PAPER NUMBER
2856	

DATE MAILED: 05/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/917,475	Applicant(s) ANDRESEN ET AL.	
	Examiner David A. Rogers	Art Unit 2856	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 May 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2 and 4-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2, and 4-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *27 July 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Response to Arguments

1. Applicant's arguments with respect to claims 1-2 and 4-17 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1, 2, 4-13, and 15-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,164,144 to Berg in view of U.S. Patent 6,042,787 to Pawliszyn, hereinafter referred to as Pawliszyn-787. Berg teaches a device to be used with Solid Phase Microextraction (SPME) comprising a pointed, open-ended needle (reference item 24) connected to a syringe (reference item 10). The needle further comprises a stationary phase coating (reference item 32) along the inner surface (reference item 30) of the needle, as seen in Figure 1B. Berg further teaches an example of using the needle where the stationary phase coating is polydimethylsiloxane (column 6, lines 10-20), a material that the applicant discloses as active materials commonly used for SPME. In use the needle is both capable of piercing a septum (reference item 84), as seen in Figure 1, and forming a seal with the septum. Berg, however, does not disclose a needle formed with holes or perforations along its length. It is well known that SPME results are optimized when the amount of sample that is exposed to the active media on the probe is increased. Methods to arrive at these optimized results include instilling motion

to the sample, e.g. agitation, stirring, or mixing. Also, increasing the amount of circulation across the active media's boundaries can also be used. In either case, increasing the amount of sample that is exposed to the active media helps to reduce the extraction time (see Berg, column 2, lines 36-40). A moving sample also helps to ensure that all of the possible analytes in the sample are exposed to the active media in order that they can be detected using devices such as gas chromatographs or mass spectrometers. It is also well known and understood in the art of sampling probes that sheaths are used to protect a sensitive member from damage due to exposure to moving media such as an agitated solution, or to other environmental concerns such as thermal shock. It is also very well known that such protective sheaths are provided with holes, perforations, or apertures in order to increase the amount of sample that the sensitive member is exposed to while also ensuring that the sensitive member is not damaged during use. In this regard Pawliszyn-787 teaches a SPME device comprising a member with an extraction coating (reference item 80) that is generally surrounded by a protective sheath (reference item 108), as seen in Figure 14. The sheath is an open-ended tubular member comprising perforations (reference item 110) along at least one section. Furthermore, the perforations are along a generally substantial portion of the tubular member's length. The open-ended, perforated sheath is provided to allow access to the fluid carrier (column 10, lines 29-31). Furthermore, as seen in Figure 2, Pawliszyn-787 teaches that is well known to develop a SPME device wherein a fiber (reference item 6) and protective sheath are extracted or retained in a pointed needle (reference item 18). By retaining the protective sheath and the fiber with its adsorbed analytes one helps to ensure that the needle is not damaged or the analytes are disturbed or lost during movement to an analysis device such as a gas chromatograph. It would have been obvious to one of ordinary

skill in the art at the time of the invention to modify the teachings of Berg with the teachings of Pawliszyn-787 to obtain a sheath for SPME where the sheath is provided with a active media coating on its inner surface, and where the sheath is provided with holes in order to increase the amount of sample that the active media is exposed to.

4. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Berg in view of Pawliszyn-787as applied to claim 10 above, and further in view of U.S. Patent 6,481,301 to Pawliszyn, hereinafter referred to as Pawliszyn-301. Berg in view of Pawliszyn-787 teaches a needle for SPME with an inner coating of phase media that adsorbs analytes from a sample. The needle of Berg is capable of piercing a septum due to its tapered tip. Berg in view of Pawliszyn-787, however, does not disclose a preferred type of material for the needle. A preferred choice for many needles is stainless steel. Stainless steel offers excellent corrosion resistance, is non-reactive to many chemicals, has the strength necessary to piece the septum, and also can be cleaned, sanitized, and reused. The use of a metal such as stainless steel would have been an obvious choice to one of ordinary skill in the art. In the event that it is not known to use stainless steel for needles in SPME environments, Pawliszyn-301 teaches a syringe for SPME where the straight-point, open-ended needle (reference item 8) is made of stainless steel. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the teachings of Berg in view of Pawliszyn-787 with the teachings of Pawliszyn-301 to obtain a SPME needle where the needle is formed from a metal or metal alloy such as stainless steel.

5. Claims 18-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berg in view of Pawliszyn-787 as applied to claims 1 and 10, respectively, and further in view of U.S. Patent 5,693,228 to Koehler *et al.* Berg teaches a needle for SPME with an inner coating of

phase media that adsorbs analytes from a sample. In combination with the teachings of Pawliszyn-787, the needle can comprise holes to allow the coating to be better exposed to the sample in order to trap the analytes that might be present in the sample. The needle of Berg is capable of piercing a septum due to its tapered tip. Berg in view of Pawliszyn, however, does not teach a needle coated with a loose, particulate material and where the holes are smaller than the grain size of the particulate material. Koehler teaches a device for SPME comprising fiber (reference item 46) in a protective sheath (reference item 57). The protective sheath and fiber are extracted from and retained in a needle (reference item 44) that further comprises a pointed tip for piercing a septum. The active coating on the fiber can be comprised of solid polymeric materials such as polydimethylsiloxane (PDMS), polyacrylate, graphite, carbowax, silicone, polyimide, octadecyltrichlorosilane, polymethylvinylchlorosilane, liquid crystalline polyacrylates, grafted self-assembled monolayers and inorganic coatings and combination of the aforementioned coatings. In the above list graphite is a well-known particulate material. Furthermore, it would have been common sense to one or ordinary skill that the holes on the needle should be smaller than the size of the particulates in order to keep the particulate matter in the needle during use. If the particulate materials were allowed to escape from the inner surface of the needle then the SPME test would be invalidated since trace analytes may have been lost. Furthermore, with regard to claims 19 and 21, the use of the specific method of cold-pressing the particulate coating in the manufacture the SPME needle is well known. In order for the particulate material to assume a generally homogenous structure one can use several techniques such as cold pressing, hot pressing, and sintering. All three techniques allow a granular material to be transformed into an essential solid material. Hot pressing and sintering require the use of

very high temperatures that may affect the structure of the needle upon which the coating is applied. Furthermore, hot pressing and sintering may drastically alter the grain structure of the particulate material such that it might not perform as well as an analyte trap for SPME. Other techniques such as bonding the particulate material using binding agents would not be preferred as these may affect the materials ability to function as a particulate trap for the analytes in a sample. Therefore, cold pressing would have been an obvious choice to form the particulate material on the inner surface since the transformed material becomes essentially solid, but it retains the necessary grain structure to perform as an analyte trap in SPME. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the teachings of Berg in view of Pawliszyn-787 with the teachings of Koehler to obtain a needle for SPME wherein the needle is coated with a particulate material in order to adsorb analytes from a sample and wherein the holes on the needle that allow the sample to circulate across the coating are sized to be smaller than the particulate material.

Conclusion

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

a. U.S. Patent 3,959,183 to Gospodar discloses general knowledge of cold pressing of particular materials to form a cohesive material that acts as a trapping agent.

b. U.S. Patent 4,732,046 to Lawrence *et al.* discloses a device to collect analytes on the inner surface of a needle, where the needle perforates a plug in a sealing-type engagement.

c. U.S. Patent 5,565,622 to Murphy discloses a device for SPME using a needle whose inner surface is coated with a stationary phase media.

d. U.S. Patent 5,691,206 to Pawliszyn discloses a device for performing SPME where it is shown that a hollow member such as a fiber can be used for SPME and that the inner surface of the hollow fiber can be coated with the trapping agent.

e. U.S. Patent 6,354,135 to McGee *et al.* discloses information regarding trapping of analytes using media such as activated charcoal.

f. U.S. Patent 6,397,658 to Villettaz *et al.* discloses a device for performing SPME using trapping agents such as polydimethylsioxane, polyarcylate, carbowax/divinylbenzene, or polydimethylsioxane/carboxene.

g. U.S. Patent 6,477,907 to Chambers *et al.* discloses methods for performing SPME using trapping agents such as polyethylene, polystyrene, and polystyrene-divinylbenzene.

h. U.S. Patent 6,495,375 to Ledig discloses methods for performing SPME using trapping agents such as activated carbon, activated alumina, silica gels, and polydimethylsiloxane.

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Rogers whose telephone number is (703) 305-4451. The examiner can normally be reached on Monday - Friday (0730 - 1600).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Hezron E. Williams can be reached on (703) 305-4705. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-7722 for regular communications and (703) 872-9319 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 306-3431.

dar
May 15, 2003

HEZRON WILLIAMS
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 2800